

PB87-158853

Guidance for the Reregistration of
Pesticide Products Containing
Metolachlor as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Jan 87



U.S. Department of Commerce
National Technical Information Service

NTIS

REPORT DOCUMENTATION PAGE		1. REPORT NO.	2.	PB87-158853	
4. Title and Subtitle Guidance for the Registration of Pesticide Products Containing METOLACHLOR as the Active Ingredient.				5. Report Date Issued January 1987	
				6.	
7. Author(s) EPA, Office of Pesticide Programs, Registration Division				8. Performing Organization Rept. No. 540/RS-87- 152	
9. Performing Organization Name and Address US Environmental Protection Agency Office of Pesticide Programs Registration Division TS-767C 401 M Street, SW Washington, DC 20460				10. Project/Task/Work Unit No.	
				11. Contract(C) or Grant(G) No. (C) (G)	
12. Sponsoring Organization Name and Address Same as #9				13. Type of Report & Period Covered	
				14.	
15. Supplementary Notes					
16. Abstract (Limit: 200 words) This document contains information regarding the registration of pesticide products containing the su active ingredient. The document includes how to register under registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.					
17. Document Analysis a. Descriptors Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.					
b. Identifiers/Open-Ended Terms					
REPRODUCED BY U.S. DEPARTMENT OF COMMERCE NATIONAL TECHNICAL INFORMATION SERVICE SPRINGFIELD, VA 22161					
c. COSATI Field/Group					
18. Availability Statement Publicly Available			19. Security Class (This Report) Unclassified		21. No. of Pages 162
			20. Security Class (This Page) Unclassified		22. Price

GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING AS THE ACTIVE INGREDIENT

METOLACHLOR
(108801)

CASE NUMBER 0001

CAS 51218-45-2

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460
JANUARY 1987

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I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.
2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.
3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request, focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide

active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;
2. Modification of product labels;
3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;
4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;
5. Modification of uses or formulation types; or
6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by the Registration Standard:

Common Name: Metolachlor
Chemical Name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide
Chemical Family: Chloroacetanilide
CAS Number: 51218-45-2
OPP (Shaughnessy) Number: 108801
Empirical Formula: $C_{15}H_{22}ClNO_2$
Trade Names: Dual, CGA-24705; Ontrack, Pennant
Physical characteristics: White to tan; Liquid; M.W.: 238.8; Boiling Point: 100 °C at 0.001 mmHg; Odorless; Solubility: 530 ppm in water at 20 °C; Miscible with xylene, toluene, dimethyl formamide, methyl cellosolve, butyl cellosolve, ethylene dichloride, and cyclohexanone; insoluble in ethylene glycol and propylene glycol; Vapor Pressure: about 10^{-5} mmHg at 20 °C.

B. Use Profile

Metolachlor is a selective herbicide registered for the control of annual grasses and broadleaf weeds in terrestrial crop areas including corn (field, sweet, and pop), sorghum, cotton, potatoes, peanuts, soybeans, green beans, kidney and other beans, blackeye and other peas, stone fruits, and tree nuts; and terrestrial noncrop areas including ornamental nursery plants and along railroads and highways. Metolachlor may be applied by conventional ground sprayer equipment and incorporated before planting, or as a preemergence herbicide applied during or after planting but before weeds or crops emerge. Applications can also be made through center pivot irrigation systems or by aircraft. Metolachlor is in a class of herbicides which are general growth inhibitors, especially of root elongation. It may also disrupt the integrity of plant cell membranes, and inhibit lipid synthesis.

Estimated total current amount of metolachlor applied in the United States is 50,000,000 pounds of active ingredient (ai) per year. Agriculture accounts for 99 percent of the usage. The major use sites and percent of crop treated are field corn (19%), soybeans (11%), sorghum (13%), and peanuts (14%).

Metolachlor was first registered for use in 1976 and is produced solely by Ciba-Geigy Corporation, Agricultural

Division, Greensboro, North Carolina from active ingredient manufactured outside the United States. Metolachlor is available as a Technical Grade Manufacturing-Use Product; an 86.4% (a.i) Emulsifiable Concentrate; 5, 15, and 25% Granulars; 27.5%, 31.8%, and 36.1% Flowable Concentrates with atrazine, a 36.3% Flowable Concentrate with propazine, and a 73.6% Emulsifiable Concentrate with metribuzin.

III. AGENCY ASSESSMENT

A. Summary

The Agency issued the original registration standard for metolachlor in 1980. The data required by that standard have been submitted and evaluated. Because of changes in the data requirements since 1980 and the finding of metolachlor in surface and ground water, new data gaps have been identified. Based on available data the Agency has reached the following conclusions. A detailed discussion of the points summarized below appears in Section B.

1. Metolachlor chronic toxicity data indicate weak evidence of oncogenicity, and is tentatively classified as showing limited evidence of carcinogenicity in animals.

2. Metolachlor has been found in several surface water surveys, some tap water samples, and in ground water in two States. Monitoring studies are required to determine the extent of contamination on a national scale.

As a result of this review, the Agency has identified additional data necessary to evaluate the environmental and human risks associated with the use of metolachlor. These data must be developed in order to maintain registration of products or to register new products containing metolachlor. A summary of these data gaps appears in Table 1. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions or revisions are necessary. These include:

Ground Water and Surface Water Advisory Statements
Crop Rotation Restriction
Endangered Species Precautionary Statements

The Regulatory Position and Rationale Section discusses the Agency's position on these restrictions and the Required Labeling section contains the specific wording required for each of the labeling revisions.

Table 1

Metolachlor - Data Gaps

(Please refer to the tables in Appendix I for detailed information regarding these requirements.)

Toxicology

Mutagenicity Studies
General Metabolism
Effects on Coagulation

Environmental Fate

Hydrolysis
Photodegradation Studies
Metabolism Studies
Mobility Studies
Accumulation Studies
Ground and Surface Water Monitoring

Product Chemistry/Residue Chemistry

Product Chemistry
Plant Metabolism
Storage Stability
Selected Residue Studies

B. Preliminary Risk Assessment

Certain data gaps exist for metolachlor and definitive conclusions cannot be made until the required data are received. The following assessment is based on the data available and is, therefore, subject to change.

1. Chronic Feeding/Oncogenicity Data. Metolachlor is considered adequately tested for chronic feeding and oncogenic effects in laboratory animals. It is considered an oncogen in rats but not in mice, as described below.

A 2-year chronic feeding/oncogenicity study with Sprague-Dawley rats was performed at Industrial Biotech Laboratories (IBT). Although validated, the study is supplementary because of several deficiencies in protocol, including dose levels which could not be verified. Conducted at dietary doses of 0, 30, 300, and 3000 ppm, the study had a statistically significant increase in primary liver neoplasms in females of the high-dose group.

A repeat chronic feeding/oncogenicity study in Sprague-Dawley rats conducted at the same dietary doses as the original study with 60 animals of each sex at each dose level had a systemic NOEL of 30 ppm (1.5 mg/kg), a systemic LEL of 300 ppm (testicular atrophy), and a statistically significant increased incidence of neoplastic liver nodules and proliferative hepatic lesions in females of the high-dose group (3000 ppm).

A valid IBT oncogenicity study conducted with Charles River CD-1 mice had no observed oncogenic potential at 30, 1000, and 3000 (429 mg/kg). A repeat oncogenicity study with Charles River CD-1 albino mice with 52 animals of each sex and at each dose level had no observed oncogenic potential at the same dose level as the original study. A decrease in body weight gain at the highest dose tested in males and females indicated that 3000 ppm was a Maximally Tolerated Dose.

2. Mutagenicity Data. Available mutagenicity information is negative.

A bacterial (*Salmonella*) system (Ames Assay) was tested for base substitutions and point mutations at 10, 100, 1000 and 10,000 μ g/plate and no increase over background mutation rates was observed.

In a mouse dominant lethal test no effects were noted on fertility rates, or on zygote or embryo survivals, after single oral doses of 100 and 300 mg/kg. No malformations of resulting embryos were reported. However, additional testing is required because of the relative insensitivity of the test.

Additional testing is required for in vitro gene mutation in a mammalian cell system, chromosomal aberration, and direct DNA damage.

3. Metabolism Data. Animal metabolism testing is needed to satisfy current requirements.

4. Subchronic Feeding Data. A 6-month subchronic study was conducted with beagle dogs in which equal numbers of males and females were dosed with metolachlor at 0 (8/8), 100 (6/6), 300 (6/6), and 1000 (8/8) ppm in the diet. Possible compound-related effects consisted of a decreased gain in body weight in males and females and a failure of the serum alkaline phosphatase to decrease with increasing age in both sexes. The NOEL in the study was 100 ppm. A reevaluation of this study indicated statistically significant decreases in activated partial thromboplastin time (APTT) in males and females at 300 and 1000 ppm. Rather than the reported error in methodology, this may be a compound-related effect. Therefore, a special study on effects of metolachlor on the blood clotting system in the dog is required. The requirement for this additional study does not impact on the NOEL of 100 ppm which has been established from the subchronic study.

5. Reproduction and Teratology Data. Metolachlor is considered to be adequately tested for teratogenic and reproductive effects. It is not considered to be either teratogenic in rats or rabbits or to cause adverse reproductive effects in rats, as discussed below.

A teratology study conducted with Sprague-Dawley rats given oral doses of 0, 60, 180, or 360 mg/kg/day of metolachlor did not affect the offspring. The only possible effect on the rats was a decrease in food consumption at the highest dose during the first one-third of the experiment which may indicate that this was the beginning of toxic maternal doses.

In a teratology study conducted with New Zealand White rabbits given oral doses of 0, 36, 120, and 360 mg/kg/day of metolachlor, no evidence of compound-induced fetotoxicity or teratogenicity was observed. Maternal toxicity was observed at the high dose.

In a two-generation reproduction study conducted with Charles River rats given oral doses of 0, 30, 300, or 1000 ppm of metolachlor, no direct effects on reproduction were shown including the highest dose. The NOEL for reproductive effects is 300 ppm based on reduced pup weights and reduced parental food consumption at 1000 ppm. Other effects that may be related to treatment were increased liver to body

weight and thyroid to body weight ratios in the 1000 ppm F₁ parents. The effects on pup weights at 1000 ppm can be considered secondary to the reduced food consumption of the dams.

6. Oncogenic Risks: The Agency has concluded that the data available constitutes limited evidence of oncogenicity under the EPA Proposed Guidelines for Carcinogen Risk Assessment (November 23, 1984, 49 FR 46294). Therefore, metolachlor is tentatively classified as a Category C carcinogen (limited evidence of carcinogenicity in animals) for the reasons given below:

- a. The oncogenic responses observed with metolachlor were confined solely to the high dose females at one site (liver) in Sprague-Dawley rats.
- b. The proliferative liver lesions were primarily benign (neoplastic nodules - 6 in 60 animals) rather than hepatocellular carcinomas (1 in 60 animals). There was no apparent difference in the time-to-occurrence of the lesions (almost all liver tumors were observed at terminal sacrifice).
- c. Metolachlor is not oncogenic in Charles River CD-1 mice.
- d. Metolachlor is not mutagenic in available assays (an Ames test and a mouse dominant lethal test).

The Agency previously made a tentative risk assessment based on the IBT rat oncogenicity study. Assuming a $Q^* = 2.1 \times 10^{-3}$ (mg/kg/day)⁻¹ and using a Theoretical Maximum Residue Contribution (TMRC) of 0.0755 mg/kg (1.5 kg diet), the "worst case" dietary risk was calculated to be 3 incidences in a million (3×10^{-6}). Using the TMRC provides a conservative estimate since it does not consider the effect of processing on residue levels in the raw agricultural commodity, that actual residue levels may be lower than the established tolerance, and that less than 100 percent of the crop is treated.

Based on preliminary exposure estimates for use of metolachlor on corn, and the Q^* from the IBT rat study, the following ranges in risk numbers were calculated:

mixer/loader (farmer): (10^{-7} - 10^{-8})
mixer/loader (custom applicator): (10^{-6} - 10^{-7})
applicator (farmer): (10^{-5} - 10^{-6})
custom applicator: (10^{-4} - 10^{-5})

7. Ground Water and Surface Water Contamination.

Metolachlor has been found in several surface water surveys. Transient peaks of 1.2 to 4.4 ppb are reported in river water possibly as a result of runoff during spring and summer. Detectable levels of metolachlor were found in some tap water samples. Metolachlor has the potential to leach and has been found in ground water in two States. Since the extent of contamination is unknown on a national scale, monitoring studies are required. A ground water advisory statement will be required on the label.

C. Other Science Findings

Environmental Fate. Available environmental fate studies provide only limited information. Although the Metolachlor Registration Standard issued in September 1980 discusses certain studies, the previously submitted data are not adequate by current standards and procedures.

Ecological Effects. Data indicate that metolachlor is practically nontoxic to birds. It is slightly toxic to aquatic invertebrates, and moderately toxic to fish.

D. Tolerance Reassessment

Tolerances have been established for residues of metolachlor and its metabolites in raw agricultural commodities, milk, eggs, meat, fat, and meat byproducts (mbyp) [40 CFR §180.368(a)] as follows:

<u>Commodities</u>	<u>Parts Per Million</u>
Almond hulls	0.3
Cattle, fat	0.02
Cattle, kidney	0.2
Cattle, liver	0.05
Cattle, meat	0.02
Cattle, mbyp (except kidney and liver)	0.02
Corn, fresh (inc. sweet, kernel plus cob with husk removed)	0.1
Corn, forage and fodder	8.0
Corn, grain	0.1
Cottonseed	0.1
Eggs	0.02

<u>Commodities</u>	<u>Parts Per Million</u>
Goats, fat	0.02
Goats, kidney	0.2
Goats, liver	0.05
Goats, meat	0.02
Goats, mbyp (except kidney and liver)	0.02
Hogs, fat	0.02
Hogs, kidney	0.2
Hogs, liver	0.05
Hogs, meat	0.02
Hogs, mbyp (except kidney and liver)	0.02
Horses, fat	0.02
Horses, kidney	0.2
Horses, liver	0.05
Horses, meat	0.02
Horses, mbyp (except kidney and liver)	0.02
Legume vegetables group foliage (except soybean forage and soybean hay)	15.0
Milk	0.02
Peanuts	0.5
Peanut, forage and hay	30.0
Peanut, hulls	6.0
Peppers, chili	0.5
Potatoes	0.2
Poultry, fat	0.02
Poultry, liver	0.05
Poultry, meat	0.02
Poultry, mbyp (except liver)	0.02
Safflower seed	0.1
Seed and pod vegetables (except soybeans)	0.3
Sheep, fat	0.02
Sheep, kidney	0.2
Sheep, liver	0.05
Sheep, meat	0.02
Sheep, mbyp (except kidney and liver)	0.02
Sorghum, forage and fodder	2.0
Sorghum, grain	0.3

<u>Commodities</u>	<u>Parts Per Million</u>
Soybeans	0.2
Soybeans, forage and hay	8.0
Stone fruits group	0.1
Tree nuts group	0.1

Tolerances have been established [40 CFR §180.368(b)] for indirect or inadvertent residues of metolachlor as a result of application of metolachlor to the growing crops listed in §180.368(a), as follows:

<u>Commodities</u>	<u>Part Per Million</u>
Barley, fodder	0.5
Barley, forage	0.5
Barley, grain	0.1
Buckwheat, fodder	0.5
Buckwheat, forage	0.5
Buckwheat, grain	0.1
Millet, fodder	0.5
Millet, forage	0.5
Millet, grain	0.1
Milo, fodder	0.5
Milo, forage	0.5
Milo, grain	0.1
Oats, fodder	0.5
Oats, forage	0.5
Oats, grain	0.1
Rice, fodder	0.5
Rice, forage	0.5
Rice, grain	0.1
Rye, fodder	0.5
Rye, forage	0.5
Rye, grain	0.1
Wheat, fodder	0.5
Wheat, forage	0.5
Wheat, grain	0.1

Canadian tolerances of 0.1 ppm have been established for residues of metolachlor in or on beans, corn, peas, potatoes and soybeans. No Mexican tolerances or Codex Alimentarius Commission Maximum Residue Limits have been established for residues of metolachlor.

EPA has evaluated the residue and toxicology data supporting these tolerances and reviewed all uses of metolachlor. Based on available data, the following conclusions have been made regarding residues of metolachlor:

- o The metabolism of metolachlor in root crops is not adequately understood. A potato metabolism study is required.
- o Storage stability data are required.
- o Processing studies are required for potatoes, soybeans, field corn, cottonseed, and peanuts.
- o Residue data are required for succulent and dried beans treated with the 25% granular formulation of metolachlor.
- o The present seed and pod vegetables commodity expression which includes okra is now obsolete. 40 CFR §180.368(a) will be editorially corrected to read beans (succulent and dry) and peas (succulent and dry).
- o All other tolerances are supported with adequate residue data.

Pending receipt of the additional studies, the Agency will evaluate new uses and new tolerances on a case-by-case basis. If the incremental risks are not significant the Agency will continue to establish new tolerances. However, the Agency does not intend to establish food additive tolerances under Section 409 of the Federal Food, Drug and Cosmetic Act due to the Delaney Clause which bars establishment of food additive regulations for substances which induce cancer in man or test animals. Comments will be solicited on this issue regarding metolachlor and other pesticides which have produced a positive oncogenic response in animal studies.

The acceptable daily intake (ADI) for metolachlor is based on the rat chronic feeding study with a NOEL of 30 ppm and a systemic LEL of 300 ppm (testicular atrophy). Using the NOEL of 30 ppm (1.5 mg/kg/day) and a safety factor of 100, the ADI is 0.015 mg/kg/day, and the maximum permissible intake (MPI) is 0.9 mg/day for a 60 kg person. The established tolerances result in a total theoretical maximum residue concentration (TMRC) of 0.0755 mg/day (1.5 kg diet) which corresponds to 8.38 percent of the MPI for a 60 kg person.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales

Based on review and evaluation of all data available on metolachlor, the Agency has made the determinations below. Refer to Section IV. D. for specific language for label revisions.

1. None of the risk criteria listed in 40 CFR 154.7 for initiating a Special Review have been met. Therefore, metolachlor is not being placed in Special Review at this time.

Rationale: After considering available toxicology data, the Agency has determined that no reason exists for placement of metolachlor in Special Review at this time. Metolachlor has tentatively been classified as a Group C carcinogen (limited evidence of carcinogenicity in animals) and appears to pose minimal risk of causing cancer in humans.

2. The Agency does not intend to establish new food additive regulations pursuant to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA)

Rationale: The Delaney Clause in Section 409 of the FFDCA bars the establishment of food additive regulations for substances which induce cancer in man or test animals, with exceptions that do not apply here. Metolachlor has been found to produce an oncogenic response in test animals. The Agency will be soliciting comments on Delaney Clause issues regarding metolachlor and other pesticides or metabolites which have produced positive oncogenic responses in chronic animal studies.

3. The Agency will continue to approve new uses for Section 3 or 24(c) registrations for metolachlor on a case-by-case basis.

Rationale: While data gaps exist in the areas of environmental fate, residue chemistry and toxicological effects, these gaps do not preclude the Agency from determining that a new use will not result in unreasonable adverse effects to humans and the environment. The Agency will review and where appropriate may approve such applications for new uses of metolachlor.

4. The Agency is requiring monitoring studies for ground water and surface water contamination.

Rationale: Metolachlor has been found in several surface water surveys and in ground water in two States. Monitoring studies are required to assess on a national scale the extent of contamination.

5. The Agency is requiring a ground water and a surface water advisory statement to appear on all end-use products with metolachlor.

Rationale: Metolachlor has been found in surface and ground water apparently as a result of its agricultural use. The label advisory statements will emphasize to users the need to exercise care when mixing and applying metolachlor in order to limit the possibility of leaching to ground water, and runoff to surface water.

6. The Agency will not require a restricted use classification for metolachlor end use products.

Rationale: Metolachlor is not acutely toxic (toxicity category III) when tested via dermal, inhalation, oral and ocular routes in rats and rabbits. Some liquid formulations containing metolachlor have been assigned toxicity II on the basis of more acutely toxic inert ingredients. Metolachlor therefore does not meet the acute toxicity criteria (40 CFR 162.11) for a restricted use classification.

7. The Agency is not requiring a reentry interval for currently registered uses of metolachlor.

Rationale: Exposure of metolachlor to field workers is not expected to be significant since metolachlor is incorporated prior to planting or applied after planting to bare ground well before growth of the crop would require entry into the treated field. Therefore, no reentry interval is required.

8. The Agency is imposing labeling restrictions on rotational crops. The extent of the restrictions will be reconsidered when additional data are submitted and reviewed.

Rationale: The Agency lacks sufficient data at the present time to determine whether planting a crop without existing tolerances in metolachlor-treated soil would result in illegal residues. Existing data indicates possible uptake into rotated crops. A 12 month planting restriction will serve to protect the public from impermissible residues in food and feed during the time necessary to generate and assess the data.

9. The Agency is requiring a full range of environmental fate studies (see data tables in Appendix I).

Rationale: Available data are insufficient to fully assess the environmental fate and transport of metolachlor. Therefore, additional data are required.

10. The Agency is requiring the following studies to support existing tolerances in agricultural commodities: potato metabolism study; storage stability data; processing studies for potatoes, soybeans, field corn, cottonseed and peanuts; residue data on succulent and dried beans treated with the 25% granular metolachlor formulation.

Rationale: Metabolism in potatoes has not been adequately defined. Storage stability has not been completely characterized. Adequate data are not available to describe residues in processed products. Residue data are required with the 25% granular product to assure that application will not exceed established tolerances in beans (dry and succulent) and peas (dry and succulent).

11. The Agency is requiring label statements regarding endangered species for all metolachlor products registered for crop uses.

Rationale: Since metolachlor is a herbicide and has crop use patterns that overlap Federally designated endangered plant habitats, label restrictions are needed to to afford protection to these endangered species.

12. While data gaps are being filled, currently registered manufacturing-use and end-use products containing metolachlor as the sole active ingredient may be sold, distributed, formulated, and used in the United States. Registrants must provide or agree to develop additional data, as specified in Tables A and B of the Data Appendix. The Agency will issue registrations for substantially similar products and will consider new uses on a case-by-case basis.

Rationale: Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency may determine not to cancel or withhold registration if data are missing or are inadequate [see FIFRA sections 3(c)(2)(B) and 3(c)(7)].

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated and the Agency will determine if the data will affect the registration of metolachlor.

B. Criteria for Registration

To be registered or reregistered under this Standard, products must contain metolachlor as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MP) must contain metolachlor as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing metolachlor provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use herbicide products only for the commodities listed below. The Use Index lists all registered uses, as well as approved maximum application rates and frequencies.

- Terrestrial, nondomestic, food uses on:
beans (succulent and dry), fresh corn, grain corn, cotton, peanuts, peas (succulent and dry), chili peppers, potatoes, safflower, sorghum, soybeans, stone fruits, and tree nuts.
- Terrestrial, nondomestic, nonfood uses on:
ornamental plants, highway and railroad rights-of-way.

D. Required Labeling

All manufacturing-use products (and end-use products, if covered by Standard) must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing metolachlor may be released for shipment by the registrant after 12 months after receipt of the Standard unless the product bears an amended label which complies with the requirements of this Standard

No pesticide product containing metolachlor may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after 24 months after receipt of the Standard unless the product bears an amended label which complies with the requirements of this Standard

In addition to the above, the following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement for each MP must list the active ingredient as:

Metolachlor

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use herbicide products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section IV.C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Precautionary Statements

Manufacturing-Use Products

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifi-

cally identified and addressed in an NPDES* permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

End-Use Products

a. Environmental Hazards for Emulsifiable Concentrates and Flowable Concentrates

Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

b. Environmental Hazards for Granules

Cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

c. Ground Water and Surface Water Advisory

Metolachlor has been identified in limited sampling of ground water and there is the possibility that it may leach through the soil to ground water, especially where soils are coarse and ground water is near the surface. Following application and during rainfall events that cause runoff, metolachlor may reach surface water bodies including streams, rivers and reservoirs.

Care must be taken when using this product to prevent back siphoning into wells, spills or improper disposal of excess pesticide, spray mixtures or rinsates.

Check valves or antisiphoning devices must be used on all mixing and/or irrigation equipment.

*National Pollution Discharge Elimination System

d. Crop Rotation Statement

Crops other than beans (succulent and dry), fresh corn, grain corn, cotton, peanuts, peas (succulent and dry), chili peppers, potatoes, safflower, sorghum, soybeans, stone fruits, tree nuts and barley, buckwheat, millet, milo, oats, rice, rye, and wheat may not be planted in metolachlor-treated soil until 12 months after application.

e. Endangered Species Statements for Products Registered for Crop Uses

It is a violation of Federal laws to use any pesticide in a manner that results in the death of endangered species or adverse modification of their habitat.

The use of this product may pose a hazard to certain Federally designated endangered species known to occur in specific areas within the CALIFORNIA counties of Merced, Sacramento and Solano. Before using this product in these counties you must obtain the EPA Endangered Species Crop Bulletin. The bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, or the Regional Office of either the U.S. Fish and Wildlife Service (Portland, Oregon) or the U.S. Environmental Protection Agency (San Francisco, California). THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE. THE USE OF THIS PRODUCT IS PROHIBITED IN THESE COUNTIES UNLESS SPECIFIED OTHERWISE IN THE BULLETIN.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing the pesticide identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to: 1) The restrictions upon use, composition, or packaging listed in Section IV; 2) The data requirements listed in Tables A and B; 3) The labeling requirements specified for manufacturing-use products in Section IV; 4) Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.¹

B. End-use products containing this pesticide are subject to: 1) The labeling requirements specified for end-use products in Section IV; 2) If not eligible for the formulator's exemption, the data requirements listed in Table A.²

¹ Data requirements are listed in the Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables. Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption.

² If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B). Two circumstances nullify this exemption: 1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A. 2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.³

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time

³ Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data, and either --

(a) Submit the existing data that you believe will satisfy the data requirements, or

(b) State that you will secure the data or have made a contract to have any necessary studies completed within the applicable time period.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned,

or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not automatically extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and
2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing-use product, these data are listed in Table B. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6(b)(1).

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Metolachlor as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

- a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.⁴
- b. Confidential Statement of Formula (EPA Form 8570-4).
- c. Formulator's Exemption Statement (EPA Form), if applicable.
- d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

- a. Two copies of any required product-specific data (See Table B).
- b. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

⁴ If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary sheet (and any supporting information) to the Office of Compliance Monitoring (OCM), which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the OCM's Laboratory Data Integrity Program at the address given at the end of this section. (Actual studies are not to be submitted to OCM.) Within 90 days of a commitment to generate data, you must submit to OCM the name and location of the laboratory carrying out each required test, along with the estimated starting date for testing. Additionally, you are to send to OCM a copy of the transmittal or cover letter for each final report submitted to the Agency. After the initial response and the dates or protocols have been committed to and accepted by the Agency, you must submit any subsequent request for time extension or protocol modification to OCM.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. End Use Products containing Metolachlor alone or in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments⁴ (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

C. Addresses

The required information must be submitted to the following address:

Richard F. Mountfort, PM-23
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

APPENDIX I
DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.
2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

TGUIDE-2

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? ¹	Bibliographic Citation ¹ /	Must Additional Data be Submitted?	Timeframe for Submission ² /
<u>\$158.120 Product Chemistry</u>						
<u>Product Identity</u>						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	N/A	N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes	6 Months
<u>Analysis and Certification of Product Ingredients</u>						
62-1 - Preliminary Analysis	TGAI	All	N/A	N/A	Yes	12 Months
<u>Physical and Chemical Characteristics</u>						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	N/A	N/A	No ³ /	
63-6 - Boiling Point	TGAI	All	N/A	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation ^{1/}	Must Additional Data be Submitted?	Timeframe for Submission ^{2/}
<u>\$158.120 Product Chemistry (cont'd)</u>						
<u>Physical and Chemical Characteristics (cont'd)</u>						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	N/A	N/A	Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	N/A	N/A	Yes	6 Months
63-9 - Vapor Pressure	PAI	All	N/A	N/A	Yes	6 Months
63-10 - Dissociation Constant	PAI	All	N/A	N/A	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	N/A	N/A	Yes	6 Months
63-12 - pH	TGAI	All	N/A	N/A	No ^{4/}	
63-13 - Stability	TGAI	All	N/A	N/A	Yes	15 Months
<u>Other Requirements</u>						
64-1 - Submittal of Samples	TGAI, PAI	All	N/A	N/A	No	

^{1/} Not applicable. Although product chemistry data have may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

^{2/} Data must be submitted within the indicated timeframe, based on the date of the Guidance Document:

6-Month Due Date August 1, 1987.
12-Month Due Date February 1, 1988.
15-Month Due Date May 1, 1988.

^{3/} Data are not required since technical is a liquid at room temperature.

^{4/} Data are not required since technical cannot be dispersed with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.125 Residue Chemistry</u>					
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00015423 00022874 00015424 00022879 00015652 00022880 00015653 00074898 00022872 00074900 00022873	Yes ^{2/}	18 Months
- Livestock	PAIRA and Plant Metabolites	Yes	00015413 00022886 00015425 00022887 00015695 00039181 00015696 00039192 00015697 00039193 00022885	No	
171-4 - Residue Analytical Method					
- Plant and Animal Residues	TGAI & Metabolites	Yes	00015432 00016306 00015543 00039176 00015466 00111693 00015698 00125227	No	
171-4 - Storage Stability	PAI	Partially	00015469	Yes ^{3/}	24 Months

TABLE A
GENERIC DATA REQUIREMENTS, FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.125 Residue Chemistry - (cont'd)</u>					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use					
- Crop Group #1 - Root and Tuber Vegetable Group ^{4/}					
o Crop 1 - Potatoes					
- Crop Field Trials	TEP	Yes	00105957 00109613 00106191	No	
- Processed Food/Feed	EP	No		Yes ^{5/}	24 Months
- Crop Group #2 - Legume Vegetables Group ^{6/}					
o Crop 1 - Beans (Succulent and Dried)					
- Crop Field Trials	TEP	Partially	00064182 00128731	Yes ^{7/}	18 Months
o Crop 2 - Peas (Succulent and Dried)					
- Crop Field Trials	TEP	Partially	00064182 00128731	Yes ^{8/}	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
\$158.125 Residue Chemistry - (cont'd)					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use (cont'd)					
o Crop 3 - Soybeans					
- Crop Field Trials	TEP	Yes	00015399 00015400 00015401 00015402 00015403 00015404 00015405 00015406 00015407 00015408 00015409 00015410 00015411 00015540 00015541 00015542 00015706 00015719 00015721 00015722 00015723 00015725	No	
			00015735 00015736 00015737 00015760 00015761 00015762 00015763 00015764 00015765 00015766 00015767 00015768 00015769 00015770 00015771 00015772 00015773 00015774 00015777 00015778 00015779 00015780		

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.125 Residue Chemistry - (cont'd)</u>					
o Crop 3 - Soybeans - (cont'd)					
- Crop Field Trials - (cont'd)			00015726 00015727 00015728 00015729	00016248 00016427 00016604 00039174	
- Processed Food/Feed	EP	No		Yes ^{9/}	24 Months
- Crop Group #3 - Foliage of Legume Vegetables Group (Except Soybean Forage, Hay and Straw)					
- Crop Field Trials	TEP	Yes	00128731	No	
o Crop 1 - Soybean Forage, Hay and Straw					
- Crop Field Trials	TEP	Yes	00015399 00015400 00015401 00015402 00015403 00015408 00015540 00015541 00015542 00015706 00015719	00015734 00015736 00015737 00015760 00015761 00015762 00015763 00015764 00015765 00015766 00015767	No

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.125 Residue Chemistry</u> - (cont'd)					
o Crop 1 - Soybean Forage, Hay and Straw - (cont'd)					
- Crop Field Trials - (cont'd)			00015721	00015768	
			00015722	00015769	
			00015725	00015770	
			00015726	00015771	
			00015727	00015772	
			00015728	00015773	
			00015729	00015774	
			00015731	00015775	
			00015732	00015777	
			00015733	00039174	
- Crop Group #4 - Fruiting Vegetables (Except Cucurbits) Group ^{10/}					
o Crop 1 - Chili Peppers					
- Crop Field Trials	TEP	Yes	00150180	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>§158.125 Residue Chemistry - (cont'd)</u>					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use					
- Crop Group #5 - Cereal Grains Group ^{11/}					
o Crop 1 - Corn, Field and Fresh					
- Crop Field Trials	TEP	Yes	00015428 00015429 00015430 00015570 00015571 00015572 00015586 00015587 00015588 00015589 00015590 00015591 00015592 00015593 00015594 00015595 00015597 00015598 00015599 00015600 00015601 00015602	00015718 00015739 00015740 00015741 00015742 00015743 00015744 00015745 00015746 00015747 00015748 00015749 00015750 00015751 00015752 00015753 00015754 00015755 00015756 00015757 00015786 00015787	No

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.125 Residue Chemistry - (cont'd)</u>					
o Crop 1 - Corn, Field and Fresh - (cont'd)					
- Crop Field Trials - (cont'd)					
			00015676	00015950	
			00015677	00015954	
			00015678	00015955	
			00015679	00016392	
			00015680	00016393	
			00015681	00016394	
			00015682	00016395	
			00015683	00016396	
			00015684	00016397	
			00015685	00016398	
			00015686	00016399	
			00015687	00016435	
			00015688	00016436	
			00015689	00016437	
			00015690	00016438	
			00015691	00016440	
			00015692	00016441	
			00015693	00016442	
			00015694	00016443	
			00015704	00016444	
			00015705	00016445	
			00015707	00016596	
			00015708	00016598	
			00015709	00017699	
			00015710	00017700	
			00015711	00078942	
			00015712	00105956	
			00015713	00109612	
			00015714	00115206	
			00015715	00125227	
			00015716		
			00015717		

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ¹ /
<u>\$158.125 Residue Chemistry - (cont'd)</u>					
o Crop 1 - Corn, Field and Fresh - (cont'd)					
- Processed Food/Feed	EP	No		Yes ¹² /	24 Months
o Crop 2 - Sorghum					
- Crop Field Trials	TEP	Yes	00015548 00016609 00015549 00016610 00015550 00016990 00015551 00016991 00015552 00016992 00016607 00011693 00016608	No	
- Crop Group #6 - Forage, Fodder, Straw of Cereal Grains Group ¹³ /					
o Crop 1 - Corn, Forage, and Silage					
- Crop Field Trials	TEP	Yes	----- ¹⁴ /	No	
o Crop 2 - Sorghum Forage, Fodder, Hay, and Silage					
- Crop Field Trials	TEP	Yes	----- ¹⁵ /	No	
- Miscellaneous Commodities					
o Crop 1 - Cotton					
- Crop Field Trials	TEP	Yes	00065047 00129058 00065048	No ¹⁶ /	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.125 Residue Chemistry - (cont'd)</u>					
o Crop 1 - Cotton - (cont'd)					
- Processed Food/Feed	EP	No		Yes <u>17/</u>	24 Months
o Crop 2 - Okra					
- Crop Field Trials	TEP	No		No <u>18/</u>	
o Crop 3 - Peanuts					
- Crop Field Trials	TEP	Yes	00015553 00015556 00015554 00015557 00015555	No	
- Processed Food/Feed	EP	No		Yes <u>19/</u>	24 Months
o Crop 4 - Safflower					
- Crop Field Trials	TEP	Yes	00084006	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ¹ /
<u>\$158.125 Residue Chemistry - (cont'd)</u>					
171-4 - Magnitude of the Residue					
- Indirect and Inadvertent Tolerances					
o Crops - Barley and Barley Fodder and Forage, Buckwheat and Buckwheat Fodder and Forage, Millet and Millet Fodder and Forage, Milo and Milo Fodder and Forage, Oat and Oat Fodder and Forage, Rice and Rice Fodder and Forage, Rye and Rye Fodder and Forage, and Wheat and Wheat Fodder and Forage					
- Crop Field Trials	TEP	Yes	00078297	No	
171-4 - Magnitude of the Residues in Meat, Milk, Poultry, and Eggs	TGAI or Plant Metabolites	Yes	00015413 00022885 00022887 00106041	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR
FOOTNOTES

\$158.125 Residue Chemistry

NOTE: All residue data requested in this Standard must be accompanied by information on the duration and conditions of sample storage prior to residue analysis, and by data depicting the stability of metolachlor residues under the conditions and for the time intervals specified, with the exception of corn stored at 15 °C for up to 13 months. Exaggerated application rates may be required to obtain detectable measurable weathered residues in or on raw agricultural commodities used for the processing studies.

1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document:

18-Month Due Date August 1, 1988.

24-Month Due Date February 1, 1989.

For Nature of the Residue in Plants and Magnitude of the Residue in Crops, the timeframes for submitting data are 18 or 24 months, as appropriate, commencing the first planting season following issuance of the Standard. These timeframes will begin with the Spring 1987 planting season and data are due no later than April 1989.

2/ Data must be submitted depicting the uptake, distribution, and metabolism of metolachlor in potatoes following foliar application. Sampling intervals through at least 21 days must be included. The identities and quantities of residue in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC and/or mass spectrometry. Data must also be presented that reflect the extraction efficiency of the solvent(s) used to remove residues following application of metolachlor to living plants.

3/ Data must be submitted depicting decline over time (longer than 13 months) of levels of residues during storage of treated commodities, under conditions (other than frozen storage at -15 °C) used in residue tests submitted in support of established tolerances on these commodities. Data must be submitted depicting the stability of metolachlor in animal products (tissues, milk, and eggs). Spiked samples should be stored at subfreezing temperatures for intervals approximating the storage intervals associated with treated samples used to determine the magnitude of the residue.

4/ If food uses are sought on other members of this crop group, residue data will be required for carrot, radish, and sugar beets.

5/ Data must be submitted depicting residues of concern in granules, chips, and dried potatoes processed from potato tubers bearing measurable weathered residues.

6/ If food uses are sought on other members of this crop group, residue data will be required for succulent beans, dry beans, succulent peas, and dry peas.

7/ Data must be submitted depicting residues of concern in or on succulent and dry beans following a single preplant incorporation or preemergence application of the 25% Granular (G) formulation at 3 lb active ingredient (ai) per Acre (A). Snap bean tests must be conducted in MI, NY, OR, and WI. Dry bean tests must be conducted in MI, CA, NE, CO, and ND.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOACHLOR
FOOTNOTES (cont'd)

\$158.125 Residue Chemistry

- 8/ Data must be submitted depicting residues of concern in or on succulent and dry peas from application of the 25% G formulation. If submitted, data conducted with succulent and dry beans may be translated to satisfy this requirement.
- 9/ Data must be submitted depicting residues of concern in meal, hulls, soapstock, crude oil, and refined oil prepared from soybeans bearing measurable weathered residues.
- 10/ If food uses are sought on other members of this crop group, residue data will be required for tomatoes and peppers.
- 11/ If food uses are sought on other members of this crop group, residue data will be required for rice and wheat.
- 12/ Data must be submitted depicting residues of concern in crude oil, refined oil, and milled products processed from field corn bearing measurable weathered residues.
- 13/ If food uses are sought on other members of this crop group, residue data will be required for wheat forage, hay, and straw.
- 14/ Bibliographic citation is identical to Crop Group #5, Crop 1 - Corn, Field and Fresh.
- 15/ Bibliographic citation is identical to Crop Group #5, Crop 2 - Sorghum.
- 16/ No tolerances have been established for the raw agricultural commodity cotton forage. Cotton use directions must continue to include feeding and grazing restrictions.
- 17/ Data must be submitted depicting residues of concern in hulls, meal, crude oil, refined oil, and soapstock processed from cottonseed bearing measurable weathered residues.
- 18/ Okra was removed from the last accepted label for the 25% G formulation. Before it can be reinstated on the labeling, data must be submitted depicting residues of concern in or on okra harvested at maturity following preplant incorporation within 14 days of planting and preemergence application of this formulation at 3 lb ai/A. Tests must be conducted in TX, GA, FL, AL, and LA, and tolerances proposed for this crop.
- 19/ Data must be submitted depicting residues of concern in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.130 Environmental Fate</u>						
<u>DEGRADATION STUDIES-LAB</u>						
161-1- Hydrolysis	TGAI or PAIRA	A, B	No		Yes	9 Months
<u>Photodegradation</u>						
161-2 - In Water	TGAI or PAIRA	A, B	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	Partially	00016301	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A, B	No		Reserved ^{2/}	
<u>METABOLISM STUDIES-LAB</u>						
162-1 - Aerobic Soil	TGAI or PAIRA	A, B	Partially	00016296	Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A, B	Partially	00015656	Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A, B	No		Reserved ^{3/}	
162-4 - Aerobic Aquatic	TGAI or PAIRA	A, B	No		Yes ^{4/}	27 Months
<u>MOBILITY STUDIES</u>						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A, B	Partially	00015676 00015659	Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No		Reserved ^{2/}	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.130 Environmental Fate - (cont'd)</u>						
164-1 - Soil	TEP	A	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	A,B	No		Reserved ^{3/}	
164-3 - Forestry	TEP	--	N/A			
164-4 - Combination and Tank Mixes	--	--	N/A			
164-5 - Soil, Long-Term	TEP	A	No		Reserved ^{5/}	
<u>ACCUMULATION STUDIES</u>						
165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	00015538 00022878 00022881	Yes 00022882 00022883	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved ^{6/}	
165-3 - Irrigated Crops	TEP	A,B	No		Reserved ^{3/}	
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	A,B	No		Reserved ^{3/}	
<u>ADDITIONAL STUDIES</u>						
- Ground and Surface Water Monitoring	TEP	A,B	Partially	00154870	Yes ^{7/}	--- Months ^{8/}

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR
FOOTNOTES

\$158.130 Environmental Fate

- 1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document:

90-Day Due Date	<u>May 2, 1987.</u>
9-Month Due Date	<u>November 1, 1987.</u>
12-Month Due Date	<u>February 1, 1988.</u>
27-Month Due Date	<u>May 1, 1989.</u>
39-Month Due Date	<u>May 1, 1990.</u>
- 2/ Data will be required based on results of the lab volatility study.
- 3/ Data will be required based on results of aquatic impact studies.
- 4/ Required since metolachlor has been found to run off and contaminate surface water systems.
- 5/ Data will be required based on results of soil metabolism and soil dissipation studies.
- 6/ Data will be required based on results of confined accumulation study.
- 7/ Studies must be designed and conducted to determine the means and extent of metolachlor's potential to leach to ground water and of metolachlor's potential to run off to surface water bodies and to contaminate drinking water drawn from surface sources.
- 8/ Protocols must be submitted within 90 days of the date of the Guidance Document. The Agency will provide the timeframe for submission of the final report.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.135 Toxicology</u>						
<u>ACUTE TESTING:</u>						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B	Yes	00015523	No	
81-2 - Acute Dermal Toxicity	TGAI	A,B	Yes	00015526	No	
- Rabbit						
81-3 - Acute Inhalation Toxicity	TGAI	A,B	Yes	00015535	No	
- Rat						
81-7 - Delayed Neurotoxicity	TGAI	A,B	No		No ^{2/}	
- Hen						
<u>SUBCHRONIC TESTING</u>						
82-1 - 90-Day Feeding:	TGAI					
- Rodent, and		A,B	No		No ^{3/}	
- Nonrodent (Dog)		A,B	Yes	00017690 00016632	No	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B	No		No ^{4/}	
82-4 - 90-Day Inhalation - Rat	TGAI	A,B	No		No ^{5/}	
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No		No ^{2/}	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.135 Toxicology - (cont'd)</u>						
83-1 - Chronic Toxicity - 2 Species:	TGAI					
- Rodent, and		A	Yes	00063398	No	
- Nonrodent (Dog)		-	N/A			
83-2 - Oncogenicity - 2 Species:	TGAI					
- Rat (preferred), and		A	Yes	00015418 00063398	No	
- Mouse (preferred)		A	Yes	00084003 00039194	No	
83-3 - Teratogenicity - 2 Species:	TGAI					
- Rat		A,B	Yes	00015396	No	
- Rabbit		A,B	Yes	00041283	No	
83-4 - Reproduction - Rat 2-Generation	TGAI	A	Yes	00080897	No	
<u>MUTAGENICITY TESTING</u>						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B	Partially	00015397	Yes ^{6/}	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission ^{1/}
<u>\$158.135 Toxicology - (cont'd)</u>						
84-2 - Structural Chromosomal Aberration	TCAI	A, B	Partially	00015630	Yes ^{7/}	12 Months
84-4 - Other Genotoxic Effects	TCAI	A, B	No		Yes	12 Months
<u>SPECIAL TESTING</u>						
85-1 - General Metabolism	PAI or PAIRA	A	No		Yes	24 Months
- Effects on Ooagulation	TCAI	A	No		Yes ^{8/}	-- Months ^{9/}

1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document:

- 6-Month Due Date August 1, 1987.
- 9-Month Due Date November 1, 1987.
- 12-Month Due Date February 1, 1988.
- 24-Month Due Date February 1, 1989.

2/ Data are not required since metolachlor is not an organophosphate.

3/ Although there is no 90-day feeding study with rodents, there is available a 2-year chronic feeding study with rats which fills this requirement.

4/ Data are not required since existing registered uses of metolachlor should not result in repeated skin contact.

5/ Data are not required since existing registered uses of metolachlor should not result in repeated inhalation exposure.

6/ Additional testing is required in an in vitro mammalian cell system.

7/ Additional testing is required in a more sensitive test system than the mouse dominant lethal test.

8/ Evaluation of the effects of metolachlor on the clotting system of the dog is required to assess the decrease in activated partial thromboplastin time (APTT) observed in the 6-month dog study.

9/ Protocols must be submitted within 6 months of the date of the Guidance Document. The Agency will provide the timeframe for submission of the final report.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>§158.140 Reentry Protection</u>						
132-1 - Foliar Dissipation	TEP	A,B	No		No ^{1/}	
132-1 - Soil Dissipation	TEP	A,B	No		No ^{1/}	
133-3 - Dermal Exposure	TEP	A,B	No		No ^{1/}	
133-4 - Inhalation Exposure	TEP	A,B	No		No ^{1/}	

^{1/} Data are not required since the existing registered uses of metolachlor are such that no human exposure of farmworkers to residues is anticipated.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>§158.145 Wildlife and Aquatic Organisms</u>						
<u>AVIAN AND MAMMALIAN TESTING</u>						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	Yes	00062465	No	
71-2 - Avian Subacute Dietary Toxicity	TGAI					
- Upland Game Bird, and		A	Yes	00016425	No	
- Waterfowl		A	Yes	00016426	No	
71-3 - Wild Mammal Toxicity	TGAI	--	N/A			
71-4 - Avian Reproduction	TGAI					
- Upland Game Bird, and		A,B	Yes	GS0001-001	No	
- Waterfowl		A,B	Yes	GS0001-002	No	
71-5 - Simulated Field Testing	TEP	--	N/A			
- Mammals, and						
- Birds						
- Actual Field Testing	TEP	--	N/A			
- Mammals, and						
- Birds						

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>\$158.145 Wildlife and Aquatic Organisms - (cont'd)</u>						
<u>AQUATIC ORGANISM TESTING</u>						
72-1 - Freshwater Fish Toxicity	TGAI					
- Coldwater Fish Species, and		A,B	Yes	00018722	No	
- Warmwater Fish Species		A,B	Yes	00018723	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	Yes	00015546	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	--	N/A			
- Fish						
- Mollusk						
- Shrimp						
72-4 - Fish Early Life Stage, and	TGAI	--	N/A			
- Aquatic Invertebrate Life Cycle						
72-5 - Fish Life-Cycle	TGAI	B	Yes	GS0001-003	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>§158.145 Wildlife and Aquatic Organisms - (cont'd)</u>						
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	--	N/A			
- Crustacean						
- Fish						
- Insect Nymph						
- Mollusk						
72-7 - Simulated Field Testing	TEP	--	N/A			
- Aquatic Organisms						
Actual Field Testing						
- Aquatic Organisms						

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>§158.145 Plant Protection</u>						
121-1 - <u>TARGET AREA PHYTOTOXICITY</u>	EP	--	No		No ^{1/} /	
<u>NONTARGET AREA PHYTOTOXICITY</u>						
<u>TIER I</u>						
122-1 - Seed Germination/Seedling Emergence	TGAI	--	No		No ^{1/} /	
122-1 - Vegetative Vigor	TGAI	--	No		No ^{1/} /	
122-2 - Aquatic Plant Growth	TGAI	--	No		No ^{1/} /	
<u>TIER II</u>						
123-1 - Seed Germination/Seedling Emergence	TGAI	--	No		No ^{1/} /	
123-1 - Vegetative Vigor	TGAI	--	No		No ^{1/} /	
123-2 - Aquatic Plant Growth	TGAI	--	No		No ^{1/} /	
<u>TIER III</u>						
124-1 - Terrestrial Field	TEP	--	No		No ^{1/} /	
124-2 - Aquatic Field	TEP	--	No		No ^{1/} /	

^{1/} These data are not required in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>§158.155 Nontarget Insect</u>						
<u>NONTARGET INSECT TESTING POLLINATORS</u>						
141-1 - Honeybee Acute Contact Toxicity	TGAI	--	No		No ^{1/}	
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	--	No		No ^{1/}	
141-4 - Honeybee Subacute Feeding Study	(Reserved)					
141-5 - Field Testing for Pollinators	TEP	--	No		No ^{1/}	

^{1/} Data are not required since the registered uses of metolachlor will not result in exposure to honeybees.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? ¹	Bibliographic Citation ¹	Must Additional Data be Submitted?	2/Timeframe for Submission
<u>\$158.120 Product Chemistry</u>						
<u>Product Identity</u>						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	N/A	N/A	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	N/A	N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	N/A	N/A	Yes	6 Months
<u>Analysis and Certification of Product Ingredients</u>						
62-1 - Preliminary Analysis	MP	All	N/A	N/A	Yes	12 Months
62-2 - Certification of Limits	MP	All	N/A	N/A	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	N/A	N/A	Yes	12 Months
<u>Physical and Chemical Characteristics</u>						
63-2 - Color	MP	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	MP	All	N/A	N/A	Yes	6 Months
63-4 - Odor	MP	All	N/A	N/A	Yes	6 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? ^{1/}	Bibliographic Citation ^{1/}	Must Additional Data be Submitted?	2/Timeframe for Submission
<u>§158.120 Product Chemistry - (cont'd)</u>						
<u>Physical and Chemical Characteristics (cont'd)</u>						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	N/A	N/A	Yes	6 Months
63-12 - pH	MP	All	N/A	N/A	No ^{3/}	
63-14 - Oxidizing or Reducing Action	MP	All	N/A	N/A	Yes	6 Months
63-15 - Flammability	MP	All	N/A	N/A	Yes	6 Months
63-16 - Explodability	MP	All	N/A	N/A	Yes	6 Months
63-17 - Storage Stability	MP	All	N/A	N/A	Yes	15 Months
63-18 - Viscosity	MP	All	N/A	N/A	Yes	6 Months
63-19 - Miscibility	MP	All	N/A	N/A	No ^{4/}	
63-20 - Corrosion Characteristics	MP	All	N/A	N/A	Yes	6 Months
<u>Other Requirements</u>						
64-1 - Submittal of Samples	MP	All	N/A	N/A	No	

TABLE B
 PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METOLACHLOR
 FOOTNOTES

\$158.120 Product Chemistry

- 1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.
- 2/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document:
 - 6-Month Due Date August 1, 1987.
 - 12-Month Due Date February 1, 1988.
 - 15-Month Due Date May 1, 1988.
- 3/ Data are not required since technical grade Manufacturing-use Product cannot be dispersed with water.
- 4/ Data are not required since technical grade Manufacturing-use Product is not an emulsifiable concentrate.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METOLACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
<u>\$158.135 Toxicology</u>						
<u>ACUTE TESTING</u>						
81-1 - Acute Oral Toxicity - Rat	MP	All	Yes	00015523	No	
81-2 - Acute Dermal Toxicity	MP	All	Yes	00015526	No	
- Rabbit						
81-3 - Acute Inhalation Toxicity	MP	All	Yes	00015535	No	
- Rat						
81-4 - Primary Eye	MP	All	Yes	00015526	No	
- Irritation - Rabbit						
81-5 - Primary Dermal	MP	All	Yes	00015530	No	
- Irritation - Rabbit						
81-6 - Dermal Sensitization - Guinea Pig	MP	All	Yes	00015631	No	

APPENDIX II
LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

<u>Size of Label on Front Panel in Square Inches</u>	<u>Signal Word Minimum Type Size All Capitals</u>	<u>"Keep Out of Reach of Children" Minimum Type Size</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

SUMMARY-3

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY
Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section III indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

SUMMARY-5

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.
[40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . ."
3	Net contents	All products	None	Bottom front panel or end of label text	"distributed by. . ." etc. May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	Must be in similar type size and run parallel to other type. May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area All products	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked. Note type size requirements.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless reference statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include box caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

<u>Criteria</u>	<u>Required Label Statement</u>
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. <u>All Other Pressurized Containers</u>	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused ¹ , dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

^{1/} Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PEST/DIS-2

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #
[40 CFR 261.33(e)])

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo- dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

PEST/DIS-3

Strychnine and salts	P108	57-24-9
		60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS
[40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichloro- phenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammmonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C ₁₆ -C ₁₈)-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

PEST/DIS-4

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethylilinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

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--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5- trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PEST/DIS-6

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

<u>PESTICIDES ON THE "F" LIST</u> <u>[40 CFR 261.33(f)]</u>	(with <u>RCRA #</u> , and <u>CAS #</u>)	
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno- 2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl- thiocarbamate) (diallate, Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2- propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

*Proposed for deletion by TCLP proposal

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Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

PEST/DIS-8

2,4,5-Trichlorophenoxyacetic acid	U232	93-76-5
(2,4,5-T)*		
[acute waste per 261.31]		
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

83 ACTIVES

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label—(i) General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely at-

tached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers—(A) Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active

ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) *Name and address of producer, registrant, or person for whom produced.* An unqualified name and address given on the label shall be considered as the name and address of the

producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation

or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement—(1) General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.*

(i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable

from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement,

type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD ₅₀	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC ₅₀	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2 thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD ₅₀	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects.....	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects.....	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(1) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines

that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(II) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(III) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the

front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed (inhaled or absorbed through skin). Do not breathe vapor (dust or spray mist). Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage (or skin irritation). Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed (inhaled or absorbed through the skin). Avoid breathing vapors (dust or spray mist). Avoid contact with skin (eyes or clothing). [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the

hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD₅₀ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD₅₀ of 100 mg/kg or less, or a subacute dietary LC₅₀ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the

pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; any valve opening.	flashback at Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 60° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers.	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 60° F.	Flammable. Keep away from heat and open flame.
Above 60° F and not over 150° F.	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on

printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repackaging for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

APPENDIX III
USE INDEX APPENDICES

EPA Index to Pesticide Chemicals

METOLACHLOR

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SAI/MAI
108801

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METOLACHLOR*

TYPE PESTICIDE: HerbicideFORMULATIONS:

Tech (95%)

G (15%, 25%)

EC (8 lb/gal)

FIC (27.5% (2.5 lb/gal), 31.8% (2.9 lb/gal), 36.1% (3.3 lb/gal), 36.3% (3.3 lb/gal))

GENERAL WARNINGS AND LIMITATIONS: A selective herbicide recommended as a preplant surface-applied, preplant incorporated, or preemergence treatment for controlling annual grasses and certain broadleaf weeds. Dry weather following preemergence applications may reduce effectiveness. Where a dosage range is given, use lower rate on coarse-textured soils or those low in organic matter; use higher rate on fine-textured soils or those high in organic matter. Apply alone or in tank mixtures by ground equipment in a minimum of 10 gallons of spray mixture per acre unless otherwise specified. Apply in water alone or in tank mixtures with listed herbicides in a minimum total volume of 2 gallons per acre by aircraft.

Agricultural Crop Tolerances (other than those listed in the text):

Peppers, chili 0.5 ppm

Indirect or Inadvertent Tolerances:

Barley, fodder 0.5 ppm

Barley, forage 0.5 ppm

Barley, grain 0.1 ppm

Buckwheat, fodder 0.5 ppm

Buckwheat, forage 0.5 ppm

Buckwheat, grain 0.1 ppm

Millet, fodder 0.5 ppm

Millet, forage 0.5 ppm

Millet, grain 0.1 ppm

Milo, fodder 0.5 ppm

Milo, forage 0.5 ppm

Milo, grain 0.1 ppm

Oats, fodder 0.5 ppm

Oats, forage 0.5 ppm

Oats, grain 0.1 ppm

Rice, fodder 0.5 ppm

Rice, forage 0.5 ppm

Rice, grain 0.1 ppm

Rye, fodder 0.5 ppm

Rye, forage 0.5 ppm

Rye, grain 0.1 ppm

Wheat, fodder 0.5 ppm

Wheat, forage 0.5 ppm

Wheat, grain 0.1 ppm

Livestock Tolerances:

Cattle, fat 0.02 ppm

Cattle, meat 0.02 ppm

Cattle, mbyp 0.02 ppm

Eggs 0.02 ppm

*2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide

Issued: 2/21/86

I-108801-1

EPA Index to Pesticide Chemicals

METOLACHLOR

GENERAL WARNINGS AND LIMITATIONS (continued)

Goats, fat	0.02 ppm
Goats, meat	0.02 ppm
Goats, mby	0.02 ppm
Hogs, fat	0.02 ppm
Hogs, meat	0.02 ppm
Hogs, mby	0.02 ppm
Horses, fat	0.02 ppm
Horses, meat	0.02 ppm
Horses, mby	0.02 ppm
Milk	0.02 ppm
Poultry, fat	0.02 ppm
Poultry, meat	0.02 ppm
Poultry, mby	0.02 ppm
Sheep, fat	0.02 ppm
Sheep, meat	0.02 ppm
Sheep, mby	0.02 ppm

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Injury may occur following use of product under abnormally high soil moisture conditions during early development of the crop.

MODE OF ACTION: The chloracetamide herbicides are general growth inhibitors, especially of root elongation. Metolachlor may disrupt the integrity of plant cell membranes, and inhibit lipid synthesis.

BROADLEAF WEEDS CONTROLLED:

PEWAIBE	Black nightshade	
PADABBA	Carpetweed	
PEDADBA	Common purslane	(a)
PCQAUBC	Florida beggarweed	(b)
PEMAEBB	Florida pusley	
PBFBOAA	Galinsoga	
PEWAIBG	Hairy nightshade	(a)
PAAAABI	Pigweed	

(a) Weeds partially controlled.

(b) Partially controlled with a minimum of 2 lb a.i./A, applied pre-emergence.

EPA Index to Pesticide Chemicals

METOLACHLOR

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCABHBB	Barnyardgrass	
PCABFAA	Crabgrass	
PCABCBA	Crowfootgrass	
PCACEBD	Fall panicum	
PCACUBC	Foxtail millet	
PCACUBA	Giant foxtail	
PCABIBA	Goosegrass	
PCACUBF	Green foxtail	
PCACWBC	Johnsongrass (seedling)	(a)
PCABLBC	Prairie cupgrass	
PCACCBA	Rice	
PCAAWAA	Sandbur	(a)
PCACWBB	Shattercane	(a)
PCAARAA	Signalgrass	
PCABLBA	Southwestern cupgrass	
PCACEBL	Texas panicum	(c)
PCACEBC	Witchgrass	
PCACUBD	Yellow foxtail	
PBMADBI	Yellow nutsedge	

(a) Weeds partially controlled.

(c) Partially controlled with a minimum of 2 lb a.i./A, applied through a center pivot irrigation system.

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations:

Preplant Surface-Applied: This is for minimum or no-tillage system only. Treated soil should not be moved out of the row or untreated soil should not be moved to the surface during planting, as weed control will be diminished.

Preplant Incorporated: Apply to soil and incorporate into top 2 inches of soil within 14 days before planting. Use preplant incorporated application if furrow irrigation is used or when a period of dry weather after application is expected. If crop will be planted on beds, apply and incorporate after bed formation unless otherwise specified.

Preemergence: Apply during planting (behind the planter) or after planting, but before weeds or crops emerge.

Center Pivot Irrigation Application: Apply alone or with tank mixtures of atrazine, or others which are registered for center pivot application. Apply in irrigation water preemergence (after planting but before weeds or crops emerge). Mixture is prepared with minimum of

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

General Warnings and Limitations (continued)

1 part water to 1 part herbicide(s). Inject mixture into center pivot system using positive displacement pump. Apply in 0.5 to 1 inch of water, using lower volume of water on coarse textured soils. More than 1 inch of water at application may reduce weed control by moving herbicide(s) below the effective zone in the soil.

001AA

Beans (garbanzo, great northern, kidney, lima, mung, navy, pinto, snap, white, and English and southern peas)

0.3 ppm (seed and pod vegetables)

General Information: Use only preemergence applications on English peas. Do not use on English peas in northeastern United States.

1.5-3
(25% G)
(8 lb/gal EC)

Preplant incorporated. The emulsifiable concentrate formulation may be tank mixed with trifluralin in dry, lima, and snap beans; or with chloramben in white, navy, kidney, pinto, and lima beans.

1.25-2.5
(8 lb/gal EC)

Preplant incorporated. Tank mix with EPTC in green or dry beans; or apply prior to a preemergence or at emergence application of dinoseb in field, lima, or snap beans.

1.5-3
(25% G)
(8 lb/gal EC)

Preemergence. The EC formulation may be tank mixed with chloramben in white, navy, kidney, pinto, and lima beans.

1.25-2.5
(8 lb/gal EC)

Preemergence. Tank mix with dinoseb in field, lima, or snap beans; or apply prior to an at emergence application of dinoseb in field, lima, or snap beans; or apply after a preplant incorporated application of EPTC in green or dry beans.

1.25-2.5
(8 lb/gal EC)

Early postemergence. Apply during early emergence when beans are in, but not beyond the crook stage. Tank mix with dinoseb in field, lima, or snap beans.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

'15005AA

Corn

0.1 ppm (fresh (including sweet, kernel plus cob
with husk removed))

0.1 ppm (grain)

1.0 ppm (fodder and forage)

1.5-4
(25% G)

or

2-4

(8 lb/gal EC)

[MAI]

1.98-3.13

(2.5 lb/gal, 3.3
lb/gal FlC)

Use limited to CO, DE, IN, IL, IA, KS, KY, MD, MI,
MN, MO, MT, NE, NY, ND, OH, PA, SD, VA, WV, WI,
and WY. Preplant. Broadcast to soil surface in
minimum or no-till systems only. Apply two-thirds
the rate as a split treatment 30 to 45 days prior
to planting, and the remaining one-third at plant-
ing. Treatments less than 30 days prior to plant-
ing may be made either as a split or single appli-
cation. Apply the lowest rate (for coarse soils)
not more than 2 weeks prior to planting.

May be formulated with atrazine.

The granular formulation may be followed with a
treatment with paraquat; or glyphosate, if weeds
are present at the time of application.

May be followed by a postemergence application of
atrazine; or atrazine and metolachlor; or 2,4-D;
or dicamba; or bromoxynil.

2-3

(8 lb/gal EC)

Use limited to CO, DE, IN, IL, IA, KS, KY, MD, MI,
MN, MO, MT, NE, NY, ND, OH, PA, SD, VA, WV, WI,
and WY. Preplant. Broadcast to soil surface in
minimum or no-till systems only.

Tank mix with atrazine; or simazine; or atrazine
and simazine.

1.49-2.5

(8 lb/gal EC)

[MAI]

1.49-2.5

(2.5 lb/gal, 3.3
lb/gal FlC)

or

1.81-2.54

(2.9 lb/gal FlC)

Preplant. Broadcast to soil surface in minimum
or no-till systems only.

Tank mix with atrazine; or cyanazine; or metola-
chlor; or simazine; or atrazine and cyanazine; or
atrazine and simazine; or atrazine and 2,4-D; or
atrazine and 2,4-D and dicamba; or cyanazine and
2,4-D; or cyanazine and 2,4-D and dicamba; or
atrazine and cyanazine and 2,4-D and dicamba; and
to each of these, may be added paraquat or glypho-
sate.

May be formulated with atrazine.

1.5-4

(25% G)

(8 lb/gal EC)

Preplant incorporated. Apply and incorporate into
the top 2 inches (4 to 6 inches in CA) of soil
within 14 days before planting. The granular
formulation may be followed by sequential applica-
tions of cyanazine; or dicamba.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance; Use; Limitations

Corn (continued)

1.25-3.5
(8 lb/gal EC)

[MAI]

1.24-2.5
(2.5 lb/gal, 3.3
lb/gal FlC)

or

1.45-2.54
(2.9 lb/gal FlC)

1.25-2.5
(8 lb/gal EC)

1.5-4
(25% G)
(8 lb/gal EC)

[MAI]

1.24-2.5
(2.5 lb/gal, 3.3
lb/gal FlC)

or

1.45-2.54
(2.9 lb/gal FlC)

1.25-2.5
(8 lb/gal EC)

1.25-3.5
(8 lb/gal EC)

2-2.5
(8 lb/gal EC)

1.25-3.5
(8 lb/gal EC)

Preplant incorporated.

Tank mix the EC formulation with atrazine; or simazine; or atrazine and simazine.

The flowable concentrate formulations are formulated with atrazine, and may be tank mixed with more atrazine; or more metolachlor; or simazine; or cyanazine.

Preplant incorporated.

Tank mix with cyanazine; or atrazine and cyanazine in field corn or silage corn only.

Preemergence.

The granular formulation may be followed by sequential applications of cyanazine; or dicamba. The flowable concentrate formulations are formulated with atrazine, and may be tank mixed with more atrazine; or more metolachlor; or simazine; or cyanazine.

Preemergence.

Tank mix with cyanazine; or atrazine and cyanazine in field corn or silage corn only.

Preemergence.

Tank mix with atrazine; or simazine; or atrazine and simazine.

Use limited to flat-planted corn in IL, IN, IA, MN, NE, OH, SD, and WI. Preemergence. Tank mix with dicamba.

Preemergence.

Tank mix with atrazine and linuron; or in the northeast United States (including MI, IN, and KY), tank mix with atrazine and pendimethalin; or simazine and pendimethalin.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Corn (continued)

1.5-2.5
(8 lb/gal EC)

Preemergence. For use in minimum or no-till systems only.

[MAI]

1.49-2.5
(2.5 lb/gal, 3.3
lb/gal FLC)

Tank mix with atrazine; or cyanazine; or linuron; or metolachlor; or simazine; or atrazine and cyanazine; or atrazine and simazine; or atrazine and 2,4-D; or atrazine and 2,4-D and dicamba; or cyanazine and 2,4-D; or cyanazine and 2,4-D and dicamba; or atrazine and cyanazine and 2,4-D and dicamba; and to each of these, may be added paraquat or glyphosate.

or
1.81-2.54
(2.9 lb/gal FLC)

May be formulated with atrazine.

1.49-2.5
(8 lb/gal EC)

Postemergence. Apply before weeds pass the 2-leaf stage, and before corn exceeds 5 inches in height. Do not apply in fluid fertilizer, or severe crop injury may occur.

[MAI]

1.49-2.5
(2.5 lb/gal, 3.3
lb/gal FLC)

Tank mix the emulsifiable concentrate formulation with atrazine.

or
1.81-2.54
(2.9 lb/gal FLC)

/23005AA

Cotton

0.1 ppm (cottonseed)

1.5-2
(8 lb/gal EC)

Use limited to AR, LA, MS, NM, OK, TN, TX, and Bootheel of MO. Preplant incorporated. Incorporate into top 1 inch of soil immediately before planting, at planting, or after planting. Plant cotton below zone of incorporation. Use on sandy loam soils only in NM, OK, and TX.

1.25-2
(8 lb/gal EC)

Use limited to NM, OK, and TX (Blacklands, Gulf Coast, Rio Grande Valley, High Plains, Rolling Plains, Edwards Plateau, and Southwest). Preplant incorporated.
Tank mix with prometryn.

1.5-2
(8 lb/gal EC)

Use limited to AR, LA, MS, NM, OK, TN, TX, and Bootheel of MO. Preemergence.

1.25-2
(8 lb/gal EC)

Use limited to NM, OK, and TX (Blacklands, Gulf Coast, Rio Grande Valley, High Plains, Rolling Plains, Edwards Plateau, and Southwest). Preemergence.
Tank mix with prometryn.

EPA Index to Pesticide Chemicals

METOLACHLOR

<u>Site, Dosage and Formulation</u> (lb a.i./A)	<u>Tolerance, Use, Limitations</u>
/15015AA <u>Okra</u>	0.3 ppm (seed and pod vegetables)
1.5-3 (25% G)	Preplant incorporated. Apply and incorporate within the surface 1 to 2 inches of soil within 14 days before planting.
1.5-3 (25% G)	Preemergence.
/15006AA <u>Peanuts</u>	0.1 ppm (peanuts) 3.0 ppm (forage and hay) 1.0 ppm (hulls)
	<u>General Information:</u> Metolachlor alone may be applied after preplant incorporated applications of benfluralin; or trifluralin; or vernam.
1.5-2 (8 lb/gal EC) or 1.5-3 (25% G)	Use limited to southeast United States. Preplant or postplant incorporated. May be followed by a sequential, cracking time treatment with sodium salt of dinoseb and sodium N-1-naphthylphthalamate.
1.25-2 (8 lb/gal EC) or 1.5-3 (25% G)	Use limited to NM, OK, and TX. Preplant or postplant incorporated. May be followed by a sequential, cracking time treatment with sodium salt of dinoseb and sodium N-1-naphthylphthalamate.
1.5-2 (8 lb/gal EC)	Preplant incorporated. Apply and incorporate up to 14 days prior to planting. Tank mix with benfluralin.
1.5-3 (25% G) (8 lb/gal EC)	Use limited to southeast United States. Preemergence. Use the highest dosage only for partial control of <u>Florida beggarweed</u> .
1.25-2 (8 lb/gal EC) or 1.5-3 (25% G)	Use limited to NM, OK, and TX. Preemergence.
1.5-3 (8 lb/gal EC)	Early postemergence. Apply at cracking time. Use the highest dosage in the southeast United States only for heavy weed infestations and better control of <u>Florida beggarweed</u> . Tank mix with sodium salt of dinoseb and sodium N-1-naphthylphthalamate.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Peas (English and
Southern)

Refer to Beans.

'14013AA

Potato

0.2 ppm

Do not harvest within 60 days after a planting to drag-off application, or within 40 days after a layby application. Do not exceed 5.5 pounds active ingredient per acre per season.

General Information: Do not use on muck or peat soils. If cool, wet soil conditions occur after application, maturity may be delayed and/or yield reduced with Superior and other early maturing varieties. Do not apply both preemergence and preplant or postplant incorporated treatments. Do not use in Kern County, CA.

1.5-3
(25% G)
(8 lb/gal EC)

Preplant or postplant incorporated. Apply and incorporate into the top 3 inches of soil preplant, or top 2 inches of soil postplant up to dragoff. Do not damage potato seed pieces or sprouts with incorporation equipment. May be followed by a preemergent application of metribuzin; or a layby application of metolachlor (see use, below).

1.5-4
(25% G)
(8 lb/gal EC)

Preemergence. The highest dosage is only used when metolachlor is applied alone where soil organic matter is between 6 to 20 percent.

1.5-3
(8 lb/gal EC)

Preemergence.
Tank mix with metribuzin; or dinoseb; or with linuron (east of the Rocky Mountains).

1.5-3
(8 lb/gal EC)

Postemergence. Directed spray. Apply up until after the last hilling.
Tank mix with metribuzin.

2.5
(8 lb/gal EC)

Layby application. Apply after hilling, at layby. This may follow an earlier incorporated or pre-emergence application of metolachlor, as long as a total of 5.5 pounds active ingredient per acre is not exceeded in a single crop season.

/08034AA

Safflower

0.1 ppm (safflower seed)

1.5-3
(8 lb/gal EC)

Preplant incorporated. Incorporated into top 2 inches of soil (4 to 6 inches in CA) within 14 days before planting.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Safflower (continued)

1.5-3
(8 lb/gal EC)

Preemergence.

/22004AA
/24006AA

Sorghum, Forage
Sorghum, Grain

0.3 ppm (grain)
2.0 ppm (forage and fodder)

Do not exceed one application per year.

General Information: If sorghum seed has not been properly treated with a safener such as N-(1,3-dioxolan-2-yl-methoxy)-iminobenzene acetonitrile, severe crop injury will result. Under high soil moisture conditions prior to sorghum emergence, injury may occur following use of metolachlor. The crop will normally outgrow this effect. Do not use on sorghum grown under dry mulch tillage or crop injury may occur. Under dry conditions, irrigate after application.

2-2.5
(8 lb/gal EC)

Use limited to CO, IL, IA, KS, MO, NE, and SD. Preplant. Broadcast to soil surface in minimum-tillage or no-tillage systems only. May be applied up to 45 days before planting. Use only split applications for treatments made 30 to 45 days prior to planting with two-thirds of the rate applied initially and the remaining one-third at planting. Treatments less than 30 days prior to planting may be made either as a split or single application. Apply the lowest rate (for coarse soils) not more than 2 weeks prior to planting. May be formulated with atrazine, or tank mixed with atrazine, for use on medium and fine soils in all of the above areas except CO. May be tank mixed with propazine in eastern CO, and central and western KS. If weeds are present at the time of treatment, metolachlor alone, formulated with or tank mixed with atrazine may be tank mixed with glyphosate; or paraquat.

[MAI]
2-2.5
(2.5 lb/gal FlC)
or
1.98-2.48
(3.3 lb/gal FlC)

1.5-2.5
(8 lb/gal EC)

Preplant incorporated. Apply and incorporate into the top 2 inches of soil within 14 days prior to planting.

1.49-2
(8 lb/gal EC)
or

Preplant incorporated.
Tank mix with, or formulated with atrazine.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Sorghum, Forage cluster (continued)

[MAI]

1.49-2

(2.5 lb/gal, 3.3
lb/gal FlC)

1.25-2.1

(8 lb/gal EC)

Preplant incorporated.

Tank mix with, or formulated with propazine; or
tank mix with terbutryn.

[MAI]

1.24-2.06

(3.3 lb/gal FlC)

1.5-2.5

(8 lb/gal EC)

Preemergence. If weeds are present at the time
of treatment, may be tank mixed with glyphosate;
or paraquat in minimum or no-till systems.

1.5-2

(8 lb/gal EC)

Preemergence.

Tank mix with, or formulated with atrazine. If
weeds are present at the time of treatment, may
be tank mixed with glyphosate; or paraquat in
minimum or no-till systems.

[MAI]

1.49-2

(2.5 lb/gal, 3.3
lb/gal FlC)

1.25-2.1

(8 lb/gal EC)

Preemergence.

Tank mix with, or formulated with propazine; or
tank mix with terbutryn.

[MAI]

1.24-2.1

(3.3 lb/gal FlC)

/28023AA

Soybeans

0.1 ppm (soybeans)

2.0 ppm (forage and fodder)

2-3

(25% G)

(8 lb/gal EC)

Use limited to CO, IL, IN, IA, KS, KY, MN, MO, MT,
NE, ND, SD, WI, and WY. Preplant. Broadcast to
soil surface in minimum-tillage or no-tillage sys-
tems only. Apply two-thirds the rate as a split
treatment 30 to 45 days prior to planting, and the
remaining one-third at planting. Treatments less
than 30 days prior to planting may be made either
as a split or single application. Apply the low-
est rate (for coarse soils) not more than 2 weeks
prior to planting.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Soybeans (continued)

1.5-2.5
(8 lb/gal EC)

Preplant. Broadcast to soil surface in minimum-tillage or no-tillage systems only.
Tank mix with linuron and paraquat; or linuron and glyphosate; or metribuzin and paraquat; or metribuzin and glyphosate.

1.5-3
(25% G)
(8 lb/gal EC)

Preplant incorporated. Apply and incorporate into the top 2 inches of soil within 14 days prior to planting.
The emulsifiable concentration formulation may be tank mixed with chloramben and metribuzin; or trifluralin.
The granular formulation may be followed by pre-emergent, sequential applications of chloramben; or dinoseb; or dinoseb and sodium N-1-naphthylphthalamate; or linuron; or metribuzin.

1.25-2.5
(8 lb/gal EC)

Preplant incorporated.
Tank mix with metribuzin; or follow with a sequential preemergence application of metribuzin.

1.5-2.5
(8 lb/gal EC)

Preplant incorporated.
Tank mix with chloramben; or follow with a sequential preemergence application of chloramben; or follow with a sequential preemergence or ground crack application of dinoseb.

1.5-3
(25% G)
(8 lb/gal EC)

Preemergence.
The emulsifiable concentrate formulation may be tank mixed with chloramben and metribuzin.

1.5-2.5
(8 lb/gal EC)

Preemergence.
Tank mix with chloramben; or dinoseb; or follow with a sequential application at ground crack of dinoseb in conventional tillage systems.
Tank mix with linuron and paraquat; or linuron and glyphosate; or metribuzin and paraquat; or metribuzin and glyphosate in minimum or no-till systems.

1.25-2.5
(8 lb/gal EC)

Preemergence.
Tank mix with metribuzin; or linuron; or dinoseb and sodium N-1-naphthylphthalamate.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

Soybeans (continued)

1.5-3
(8 lb/gal EC)

Early postemergence. Apply when soybeans are still in the cotyledon stage, before leaves open to expose the terminal bud.
Tank mix with dinoseb.

1.5-2.5
(8 lb/gal EC)

Early postemergence. Apply as late as ground cracking.
Tank mix with dinoseb.

1.25-2.5
(8 lb/gal EC)

Early postemergence. Apply through the crook stage, anytime from soil cracking to before the soybean true leaves open.
Tank mix with dinoseb and sodium N-1-naphthylphthalamate.

TERRESTRIAL NON-FOOD CROP

(Ornamental Plants and Forest Trees)

General Warnings and Limitations: Do not use on seedbeds, on unrooted cuttings, or prior to transplanting. Do not apply granules to wet ornamental foliage. Do not use in greenhouses or other enclosed structures. Do not make more than 2 applications per year.

/34149DA
/34070DA
/35073DA
/31458DA

Aucuba
Holly
Juniper
Liriope (Silver
Sunproof)

1.95-4.05
(15%, 25% G)

Broadcast, using a cyclone or similar type applicator. Apply to established ornamentals or to ornamentals transplanted for at least 5 days. Simazine may be applied just before or after metolachlor treatment for control of annual broad-leaf weeds.

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)Tolerance, Use, Limitations

/35142DA	<u>American Holly</u>
/35315DA	<u>Andorra Juniper</u>
/35021DA	<u>Arborvitae*</u>
/34149DA	<u>Aucuba*</u>
/34500DA	<u>Azalea (Hershey Red, Herbert, Purple Splendor)</u>
/35342DA	<u>Bar Harbor Juniper</u>
/34031DA	<u>Boxwood</u>
/34045DA	<u>Cotoneaster*</u>
/35056DA	<u>Crabapple*</u>
/35160DA	<u>Creeping Juniper</u>
/34537DA	<u>Dwarf Japanese Yew*</u>
/34052DA	<u>English Ivy</u>
/34053DA	<u>Euonymus</u>
/34058DA	<u>Firethorn</u>
/34062DA	<u>Forsythia</u>
/35338DA	<u>Hicks Yew</u>
/34072DA	<u>Honeysuckle</u>
/34238DA	<u>Hybrid Tea Roses</u>
/34078DA	<u>Japanese Andromeda*</u>
/34080DA	<u>Japanese Holly*</u>
/35187DA	<u>Japanese Maples</u>
/34087DA	<u>Leucothoe*</u>
/34089DA	<u>Lilac (James McFar- land)</u>
/31458DA	<u>Liriope* (Silver Sun- proof)</u>
/35083DA	<u>Maple*</u>
/34245DA	<u>Mentor Barberry</u>
/34097DA	<u>Mountain-Laurel</u>
/34199DA	<u>Osmanthus*</u>
/34106DA	<u>Pachysandra</u>
/34088DA	<u>Privet</u>
/33117DA	<u>Purpleleaf Winter- creeper</u>
/35105DA	<u>Red Oak</u>
/34277DA	<u>Red Osier Dogwood</u>
/34118DA	<u>Rhododendron*</u>
/34120DA	<u>Rose (miniature)</u>
/34314DA	<u>Rosebay Rhododendron</u>
/35209DA	<u>Shore Juniper</u>
/34130DA	<u>Spirea</u>
/34453DA	<u>Spring Glory For- sythia</u>
/34137DA	<u>Viburnum</u>
/34536DA	<u>Warty Barberry</u>
/34140DA	<u>Weigela*</u>
/34291DA	<u>Wintergreen Barberry</u>

EPA Index to Pesticide Chemicals

METOLACHLOR

Site, Dosage
and Formulation
(lb a.i./A)

Tolerance, Use, Limitations

American Holly cluster (continued)

1.95-4.05
(15%, 25% G)
or
2-3
(8 lb/gal EC)

Broadcast to established ornamentals or to ornamentals at least 5 days after transplanting. Apply the granular formulation with a cyclone or similar type applicator.
The EC formulation may be tank mixed with simazine; or simazine may be applied just before or after any metolachlor treatment to those field and liner grown ornamentals marked with an asterisk.

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

/67004AA

Highway Rights-of-Way N.F.

[MAI]
1.25
(2.5 lb/gal, 3.3
lb/gal FlC)

Use limited to CO, KS, MT, NE, ND, SD, and WY. Broadcast for weed control in established perennial grasses along roadsides. Apply in the fall before ground freezes, or after thawing in the spring. Apply only once per year. Formulated with atrazine.

/67005AA

Railroad Rights-of-Way

N.F.

4
(8 lb/gal EC)

Broadcast. Apply immediately prior to weed emergence in 50 to 100 gallons of water per acre. The tank mix with atrazine may be applied after weeds emerge, but before they reach 6 inches in height. Tank mix with atrazine; or simazine.

EPA Index to Pesticide Chemicals

METOLACHLOR

Listing of Registered Pesticide Products by Formulation

6095.0001	<u>95% technical chemical</u> metolachlor (108801) 000100-00587			
6015.0004	<u>15% granular</u> metolachlor (108801) 000100-00627			
6025.0004	<u>25% granular</u> metolachlor (108801) 000100-00638			
6286.4012	<u>86.4% (8 lb/gal) emulsifiable concentrate</u> metolachlor (108801) 000100-00597 000100-00610			
	(000100-00597)	AZ83000500	IA79000500	IA83000100
		MD79001000	NM85000400	TX83001100
6227.5014	<u>27.5% (2.5 lb/gal) flowable concentrate</u> metolachlor (108801) plus atrazine (080803) 000100-00590			
	(000100-00590)	IA83000200	OK82002900	
6231.8014	<u>31.8% (2.9 lb/gal) flowable concentrate</u> metolachlor (108801) plus atrazine (080803) 000100-00623			
6236.1014	<u>36.1% (3.3 lb/gal) flowable concentrate</u> metolachlor (108801) plus atrazine (080803) 000100-00645			
6236.3014	<u>36.3% (3.3 lb/gal) flowable concentrate</u> metolachlor (108801) plus propazine (080808) 000100-00604			

EPA Index to Pesticide Chemicals

METOLACHLOR

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

<u>Chemical Code</u>	<u>Common Name (source)</u>	<u>EPA Acceptable Common/Chemical Name</u>
080803	—	atrazine
080808	—	propazine

— Use EPA Acceptable Common/Chemical Name

EPA Index to Pesticide Chemicals

METOLACHLOR

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

<u>Chemical Code</u>	<u>Common Name (source)</u>	<u>EPA Acceptable Common/Chemical Name</u>
101101	metribuzin	4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one
080803	—	atrazine
084301	benfluralin (ISO)	N-butyl-N-ethyl-alpha,alpha,alpha-trifluoro-2,6-dinitro-p-toluidine
029901	—	chloramben
100101	cyanazine (ISO)	2-[[4-chloro-6-(ethylamino)-S-triazin-2-yl]-amino]-2-methyl propionitrile
029801	—	dicamba
030001	2,4-D	2,4-dichlorophenoxyacetic acid
037505	—	dinoseb
037512	—	dinoseb, sodium salt
041401	EPTC	S-ethyl dipropylthiocarbamate
108501	pendimethalin (ANSI)	N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine
103601	glyphosate	glyphosate, isopropylamine, salt of
035506	—	linuron
061601	paraquat	paraquat dichloride
080805	—	prometryn
080808	—	propazine
041404	vernarn	S-propyl dipropylthiocarbamate
080807	—	simazine
030703	—	sodium N-1-naphthylphthalamate
080813	—	terbutryn

Issued: 2/21/86

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METOLACHLOR

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes
(continued)

<u>Chemical</u> <u>Code</u>	<u>Common Name</u> <u>(source)</u>	<u>EPA Acceptable</u> <u>Common/Chemical Name</u>
036101	--	trifluralin

-- Use EPA Acceptable Common/Chemical Name

EPA Index to Pesticide Chemicals

METOLACHLOR

Auxiliary Documentation

#100-645 (Bicep 6L) has a 2.64-3.55 lb a.i./A dosage range for sorghum (from table 5), which is much higher than the "normal" rate of 1.5-2 lb a.i./A. I did not extend the entry's dosages to reflect this rate.

#100-597 (dual 8E) in the paragraph dealing with soybean tank mix/sequential application with metribuzin, they refer to a table 5 for dosages. I assumed table 7 to be the correct one and used it for the dosage calculation.

#100-638 (dual 25G) in the soybean, reduced-till, preplant surface application, does not give a dosage rate. The later mention of "2 lb a.i./A" on coarse soils not more than 2 weeks prior to planting" coincides with the dual 8E label; it's the medium and fine texture soil dosages that were lacking. I assumed 2-3 lb a.i./A to be the complete coarse to fine dosage range as was on the dual 8E label. Table 3 is not likely to be intended for this use because the coarse soil rate of 2 lb a.i./A is higher than the lowest rate in table 3; this coincides with other no-till vs. conventional till rates elsewhere in the labeling.

#100-597 (dual 8E) in final soybean use for no-till with metribuzin or linuron and paraquat or glyphosate, does not specify application timing. I assumed both preplant and preemergence.

APPENDIX IV
BIBLIOGRAPHY APPENDICES

APPENDIX IV

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

- a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.
- b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00015397	Arni, P.; Muller, D. (1976) Salmonella/Mammalian--Microsome Mutagenicity Test. (Unpublished study received Jan 19, 1977 under 100-583; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095768-F)
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APPENDIX V
FORMS APPENDICES

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET		EPA REGISTRATION NO.
PRODUCT NAME		
APPLICANT'S NAME		DATE GUIDANCE DOCUMENT ISSUED
With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:		
☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:		
☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:		
NAME OF OTHER REGISTRANT		
☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:		
☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):		
☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)		
REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

**CERTIFICATION OF ATTEMPT TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA**

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE
	ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No. _____ Date _____

Guidance Document for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submit- ting Data (At- tached)	
\$158.120 PRODUCT CHEMISTRY	-				
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk- density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submit- ting Data (At- tached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explosibility				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric break- down voltage				
\$158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitiza- tion				

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. _____ Product Name _____

Applicant's Name and Address _____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): _____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 9570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient

Source: Product name and Reg. No.

_____	_____
_____	_____
_____	_____

Signature _____

Date _____ Title _____